

110TH CONGRESS
2D SESSION

H. R. 7199

To establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2008

Mr. CANNON introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Medical Information
5 and Treatment Access Act".

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Findings.

**TITLE I—FEDERAL INTERNET SITE FOR CONSOLIDATION AND
TRANSLATION OF INFORMATION ON DISEASES AND OTHER
CONDITIONS**

Sec. 101. Internet site.

**TITLE II—ADDITIONAL FORUMS FOR EXCHANGE OF HEALTH
INFORMATION**

Sec. 201. Forum regarding off-label uses of new drugs and devices.

Sec. 202. John Eisenberg forum regarding surgical procedures.

Sec. 203. John Eisenberg forum regarding complementary and alternative medicine; dietary supplements and food.

TITLE III—GENERAL PROVISIONS

Sec. 301. Definitions.

Sec. 302. Effective dates.

1 SEC. 3. FINDINGS.

2 The Congress finds as follows:

3 (1) The Congress and the American people de-
4 sire to live healthy lives and foster an effective and
5 efficient health care system. This system requires
6 timely, accurate, and ever-improving information re-
7 sources. This will foster maximization of health care
8 outcomes and help health care practitioners and pa-
9 tients partner for more effective results.

10 (2) The Internet is a unique tool offering access
11 to great volumes of information. Some is accurate
12 and some is not. There has also been extensive gov-
13 ernment investment in placing medical information
14 on the Internet in many diverse places.

15 (3) There is a need to consolidate and translate
16 this myriad of information for physicians and con-
17 sumers, from the listing of clinical trials to the pro-

1 tocols for treatment of various diseases and condi-
2 tions, as well as the integration of new discoveries
3 and the evaluations of outcomes-based examinations
4 of drugs and devices for conditions other than those
5 for which they are already approved. This will lead
6 to more accurate treatment, fewer medical errors,
7 and more successful outcomes, while also protecting
8 patients, a physician's right to practice medicine,
9 and a patient's right to access the health care the
10 patient desires.

11 (4) The Food and Drug Administration is
12 uniquely qualified to assist the Nation in fulfilling
13 this mission to improve health care for the benefit
14 of Americans. The Administration already coordi-
15 nates the information needs of many government
16 agencies and equivalent regulatory bodies in other
17 countries.

18 (5) In providing Internet-based forums for ob-
19 taining and disseminating health-related information
20 (including information on surgical procedures; com-
21 plimentary and alternative medicine; dietary supple-
22 ments and food; and unapproved treatments), the
23 Food and Drug Administration should work closely
24 with educational institutions, schools of medicine,
25 and other appropriate private entities and ensure

1 that the expertise of such entities is appropriately
2 utilized.

3 **TITLE I—FEDERAL INTERNET**
4 **SITE FOR CONSOLIDATION**
5 **AND TRANSLATION OF INFOR-**
6 **MATION ON DISEASES AND**
7 **OTHER CONDITIONS**

8 **SEC. 101. INTERNET SITE.**

9 (a) IN GENERAL.—The Secretary of Health and
10 Human Services, acting through the Commissioner of
11 Food and Drugs, shall carry out a program whose mission
12 is, through an Internet site maintained for purposes of
13 the program—

14 (1) to consolidate and translate health care in-
15 formation that is available to the public from Fed-
16 eral agencies, linking the various health-related
17 Internet sites of such agencies; and

18 (2) to assist in the translation and reporting of
19 disease or condition protocols for physicians and lay
20 persons.

21 (b) INFORMATION ON DISEASES AND OTHER CONDI-
22 TIONS.—The Secretary shall ensure that the Internet site
23 under subsection (a) has capacities that enable a user of
24 the site to enter the name of a disease or other health
25 condition and obtain Internet links appropriate to health

1 care providers, and links appropriate to lay persons, that
2 provide—

3 (1) an explanation of the health condition; and

4 (2) information on all available treatment pro-
5 tocols, including—

6 (A) standard medical practice protocols;

7 and

8 (B) any clinical trials, and any outcomes-
9 based treatment protocols, that—

10 (i) are being conducted or supported
11 by the National Institutes of Health;

12 (ii) are included in the registry and
13 results data bank under section 402(j) of
14 the Public Health Service Act (42 U.S.C.
15 282(j));

16 (iii) are being conducted pursuant to
17 the Federal Food, Drug, and Cosmetic Act
18 or section 351 of the Public Health Service
19 Act;

20 (iv) are being conducted pursuant to
21 section 201 of this Act; or

22 (v) are identified pursuant to section
23 201 or 202 of this Act or pursuant to sec-
24 tion 485D(i) of the Public Health Service
25 Act (as added by section 203 of this Act).

1 (c) FEDERAL DATABASES.—Internet links under
2 subsection (b) shall include the following:

3 (1) Links that provide information on how to
4 enroll in a clinical trial referred to in subsection
5 (b)(2)(B) and how to be treated under an outcomes-
6 based treatment protocol referred to in such sub-
7 section.

8 (2) Links to Federal electronic databases that
9 are available to the public and provide disease-spe-
10 cific or condition-specific information, including such
11 databases of the National Institutes of Health, the
12 Centers for Disease Control and Prevention, and the
13 Food and Drug Administration.

14 (3) A link to the Internet site under section
15 204(a) (relating to research and treatments carried
16 out pursuant to section 201, and the identity of the
17 health care practitioners involved).

18 (4) A link to the Internet sites under sections
19 201 and 202 of this Act and the Internet site under
20 section 485D(i) of the Public Health Service Act (as
21 added by section 203 of this Act).

22 (d) DATE CERTAIN FOR OPERATION OF PROGRAM.—
23 The Internet site under subsection (a) shall be established
24 and ready for use by health care practitioners and lay per-

1 sons not later than two years after the date of the enact-
2 ment of this Act.

3 **TITLE II—ADDITIONAL FORUMS**
4 **FOR EXCHANGE OF HEALTH**
5 **INFORMATION**

6 **SEC. 201. FORUM REGARDING OFF-LABEL USES OF NEW**
7 **DRUGS AND DEVICES.**

8 (a) IN GENERAL.—The Secretary, acting through the
9 Commissioner of Food and Drugs, shall (directly or
10 through contract) establish a program under which the
11 following occur:

12 (1) Health care practitioners submit to the Sec-
13 retary information obtained in the course of their
14 professional practices regarding off-label uses of new
15 drugs and devices.

16 (2) The Secretary maintains the information re-
17 ceived under paragraph (1); makes such information
18 available to health care practitioners and the general
19 public through one or more Internet sites; and re-
20 ceives, maintains, and makes available through such
21 site appropriate comments and information provided
22 in response to such information.

23 (3) The Secretary carries out paragraph (2) in
24 a manner reasonably calculated to provide a forum

1 for obtaining and disseminating information, includ-
2 ing clinical data, toward the following goals:

3 (A) Identifying off-label uses of new drugs
4 and devices that are reasonable candidates for
5 approval under section 505 or 515 of the Fed-
6 eral Food, Drug, and Cosmetic Act or under
7 section 351 of the Public Health Service Act.

8 (B) Identifying off-label uses of new drugs
9 and devices that constitute a threat to the pub-
10 lic health.

11 (C) Making available to the Secretary in-
12 formation for uses with respect to promoting in-
13 novations in evidence-based clinical practice and
14 health care technologies under title IX of the
15 Public Health Service Act.

16 (b) VOLUNTARY PARTICIPATION.—Subsection (a)
17 may not be construed as requiring that any health care
18 practitioner or other person participate in the program
19 under such subsection.

20 (c) CERTAIN AUTHORITIES.—The posting by the Sec-
21 retary of information on an Internet site under subsection
22 (a) is subject to the following:

23 (1) The Secretary may not post information
24 submitted by a health care practitioner unless the
25 practitioner authorizes the Secretary to include in

1 the posting the identity and the business address of
2 the practitioner.

3 (2) The Secretary may impose reasonable re-
4 strictions on the format and volume of information
5 to be posted and on the frequency of postings.

6 (d) CRITERIA.—Not later than one year after the
7 date of the enactment of this Act, the Secretary shall by
8 regulation issue criteria for carrying out this section.

9 **SEC. 202. JOHN EISENBERG FORUM REGARDING SURGICAL**
10 **PROCEDURES.**

11 (a) IN GENERAL.—The Secretary, acting through the
12 Commissioner of Food and Drugs, shall (directly or
13 through contract) establish a program under which the
14 following occur:

15 (1) Health care practitioners submit to the Sec-
16 retary information obtained in the course of their
17 professional practices regarding surgical procedures.

18 (2) The Secretary maintains the information re-
19 ceived under paragraph (1); makes such information
20 available to health care practitioners and the general
21 public through one or more Internet sites; and re-
22 ceives, maintains, and makes available through such
23 site appropriate comments and information provided
24 in response to such information.

1 (3) The Secretary carries out paragraph (2) in
2 a manner reasonably calculated to provide a forum
3 for obtaining and disseminating information, includ-
4 ing clinical data, toward the following goals:

5 (A) Identifying innovative surgical proce-
6 dures.

7 (B) Identifying surgical procedures that
8 constitute a threat to the public health.

9 (C) Making available to the Secretary in-
10 formation for uses with respect to promoting in-
11 novations in evidence-based clinical practice and
12 health care technologies under title IX of the
13 Public Health Service Act.

14 (b) VOLUNTARY PARTICIPATION.—Subsection (a)
15 may not be construed as requiring that any health care
16 practitioner or other person participate in the program
17 under such subsection.

18 (c) CERTAIN AUTHORITIES.—The posting by the Sec-
19 retary of information on an Internet site under subsection
20 (a) is subject to the following:

21 (1) The Secretary may not post information
22 submitted by a health care practitioner unless the
23 practitioner authorizes the Secretary to include in
24 the posting the identity and the business address of
25 the practitioner.

1 (2) The Secretary may impose reasonable re-
 2 strictions on the format and volume of information
 3 to be posted and on the frequency of postings.

4 (d) CRITERIA.—Not later than one year after the
 5 date of the enactment of this Act, the Secretary shall by
 6 regulation issue criteria for carrying out this section.

7 **SEC. 203. JOHN EISENBERG FORUM REGARDING COM-**
 8 **PLEMENTARY AND ALTERNATIVE MEDICINE;**
 9 **DIETARY SUPPLEMENTS AND FOOD.**

10 Section 485D of the Public Health Service Act is
 11 amended—

12 (1) by redesignating subsections (i) and (j) as
 13 subsections (j) and (k), respectively; and

14 (2) by adding after subsection (h) the following
 15 subsection:

16 “(i) JOHN EISENBERG FORUM FOR EXCHANGE OF
 17 INFORMATION.—

18 “(1) IN GENERAL.—The Director of the Center,
 19 in consultation with the Commissioner of Food and
 20 Drugs, shall (directly or through contract) establish
 21 a program under which the following occur:

22 “(A) Health care practitioners submit to
 23 the Director information obtained in the course
 24 of their professional practices regarding com-
 25 plementary and alternative treatment, diag-

1 nostic and prevention modalities, disciplines and
2 systems.

3 “(B) The Director maintains the informa-
4 tion received under subparagraph (A); makes
5 such information available to health care practi-
6 tioners and the general public through estab-
7 lishing one or more Internet sites; and receives,
8 maintains, and makes available through such
9 site appropriate comments and information pro-
10 vided in response to such information.

11 “(C) The Director carries out subpara-
12 graph (B) in a manner reasonably calculated to
13 provide a forum for obtaining and dissemi-
14 nating information, including clinical data, to-
15 ward the following goals:

16 “(i) Identifying alternative treatment,
17 diagnostic and prevention systems, modal-
18 ities, and disciplines that should be inte-
19 grated with the practice of conventional
20 medicine as a complement to such medi-
21 cine and integrated into health care deliv-
22 ery systems in the United States.

23 “(ii) Identifying any alternative med-
24 ical practices or procedures that constitute
25 a threat to the public health.

1 “(iii) Making available to the Commis-
2 sioner of Food and Drugs information for
3 uses with respect to promoting innovations
4 in evidence-based clinical practice and
5 health care technologies under title IX of
6 the Public Health Service Act.

7 “(2) DIETARY SUPPLEMENTS AND FOOD.—In
8 consultation with the Commissioner of Food and
9 Drugs, the Director of the Center shall carry out the
10 following:

11 “(A) Activities under paragraph (1) shall
12 include carrying out such paragraph with re-
13 spect to information that relates to the effects
14 of dietary supplements and food on diseases
15 and disorders and is obtained by the practi-
16 tioners in the course of their professional prac-
17 tices and submitted to the Director.

18 “(B) With respect to paragraph (1)(C) as
19 applied for purposes of this paragraph, the
20 goals shall be the following:

21 “(i) Identifying dietary supplements
22 and food and uses of such supplements
23 and food that are of clinical benefit in
24 treating particular diseases or disorders.

1 “(ii) As appropriate, providing for the
2 publication of authoritative statements,
3 within the meaning of section
4 403(r)(3)(C)(i) of the Federal Food, Drug,
5 and Cosmetic Act, about the relationship
6 between a nutrient and a disease or health-
7 related condition.

8 “(iii) Carrying out paragraph
9 (1)(C)(iii) with respect to dietary supple-
10 ments.

11 “(3) VOLUNTARY PARTICIPATION.—Paragraph
12 (1) may not be construed as requiring that any
13 health care practitioner or other person participate
14 in the program under such paragraph.

15 “(4) CERTAIN AUTHORITIES.—The posting by
16 the Director of the Center of information on the
17 Internet site under paragraph (1) is subject to the
18 following:

19 “(A) The Director may not post informa-
20 tion submitted by a health care practitioner un-
21 less the practitioner authorizes the Director to
22 include in the posting the identity and the busi-
23 ness address of the practitioner.

24 “(B) The Director may impose reasonable
25 restrictions on the format and volume of infor-

1 mation to be posted and on the frequency of
2 postings.

3 “(5) CRITERIA.—Not later than one year after
4 the date of the enactment of the Medical Informa-
5 tion and Treatment Access Act, the Secretary shall
6 by regulation issue criteria for carrying out this sub-
7 section.

8 “(6) DEFINITIONS.—For purposes of this sub-
9 section, the terms ‘dietary supplement’ and ‘food’
10 have the meaning given such terms in section 201
11 of the Federal Food, Drug, and Cosmetic Act.”.

12 **TITLE III—GENERAL** 13 **PROVISIONS**

14 **SEC. 301. DEFINITIONS.**

15 For purposes of this Act:

16 (1) The terms “device”, “labeling”, and “new
17 drug” have the meanings given such terms in section
18 201 of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 301).

20 (2) The term “off-label use”, with respect to a
21 new drug or a device, means a use not included in
22 the labeling approved for the drug or device pursu-
23 ant to section 505, 510, or 515 of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 355, 360c,



1 360e) or section 351 of the Public Health Service
2 Act (42 U.S.C. 262).

3 (3) The term "Secretary" means the Secretary
4 of Health and Human Services.

5 **SEC. 302. EFFECTIVE DATES.**

6 (a) IN GENERAL.—Subject to subsection (b)—

7 (1) sections 201 and 202 take effect on the
8 date on which a final rule takes effect pursuant to
9 sections 201(d) and 202(d), respectively; and

10 (2) the amendment made by section 203 takes
11 effect on the date on which the final rule required
12 under section 485D(i)(5) of the Public Health Serv-
13 ice Act (as added by such amendment) takes effect.

14 (b) ISSUANCE OF CRITERIA.—Sections 201(d) and
15 202(d) of this Act and section 485D(i)(5) of the Public
16 Health Service Act (as added by section 203 of this Act)
17 take effect on the date of the enactment of this Act.

○